

Amendments to the Claims

1. (original) A breath-actuated delivery device, comprising:
a delivery unit which is actuatable to deliver substance on application of a delivery force thereto;
a loading unit which is actuatable to apply the delivery force to the delivery unit to actuate the same;
a mouthpiece through which a subject in use exhales;
an air channel which is in fluid communication with the mouthpiece; and
an actuating member which is disposed in the air channel, the actuating member comprising a flexible, bi-stable element which is actuatable, on exhalation by the subject into the mouthpiece, between a first, non-actuated state and a second, actuated state in which the actuating member actuates the loading unit to apply the delivery force to the delivery unit to actuate the same.

2. (original) The delivery device of claim 1, wherein the delivery unit comprises a pump unit.

3. (original) The delivery device of claim 2, wherein the pump unit is configured to deliver an aerosol.

4. (original) The delivery device of claim 2, wherein the pump unit is configured to deliver a jet.

5. (currently amended) The delivery device of ~~any of claims 1 to 4~~ claim 1, wherein the substance comprises a liquid.

6. (currently amended) The delivery device of ~~any of claims 1 to 4~~ claim 1, wherein the substance comprises a powder.

7. (original) The delivery device of claim 1, wherein the delivery unit comprises an aerosol canister which is configured to deliver an aerosol.

8. (original) The delivery device of claim 1, wherein the delivery unit comprises a liquid delivery unit.

9. (original) The delivery device of claim 1, wherein the delivery unit comprises a powder delivery unit.

10. (currently amended) The delivery device of claim 8 ~~or~~ 9, wherein the delivery unit is configured to deliver an aerosol.

11. (currently amended) The delivery device of claim 8 ~~or~~ 9, wherein the delivery unit is configured to deliver a jet.

12. (currently amended) The delivery device of ~~any of claims 1 to 11~~ claim 1, wherein the loading unit comprises a drive member which is actuatable from a loaded position to actuate the delivery unit, a biasing element for loading the drive member with the delivery force, and a restraining member for normally restraining the drive member in the loaded position and being configured to be released on actuation of the actuating member to the actuated state, such as to cause the biasing element to drive the drive member to actuate the delivery unit.

13. (original) The delivery device of claim 12, wherein the restraining member comprises a tether which is broken on actuation of the actuating member.

14. (original) The delivery device of claim 13, wherein the tether comprises at least one filament.

15. (original) The delivery device of claim 14, wherein the tether comprises a plurality of filaments.

16. (currently amended) The delivery device of claim 14 ~~or~~ 15, wherein the at least one filament comprises a strand.

17. (currently amended) The delivery device of claim 14 ~~or 15~~, wherein the at least one filament comprises a sheet.

18. (currently amended) The delivery device of ~~any of claims 14 to 17~~ claim 14, wherein the at least one filament is formed of a notch-sensitive material.

19. (original) The delivery device of claim 18, wherein the at least one filament is axially stretched such as to be notch sensitized.

20. (original) The delivery device of claim 12, wherein the restraining member comprises a gas support cushion which is vented on -actuation of the actuating member.

21. (original) The delivery device of claim 20, wherein the gas support cushion is ruptured on actuation of the actuating member.

22. (currently amended) The delivery device of ~~any of claims 12 to 21~~ claim 12, wherein the drive member and the restraining member are formed as a single integral unit.

23. (currently amended) The delivery device of ~~any of claims 12 to 22~~ claim 12, wherein the loading unit further comprises a loading member which is operable to load the biasing element with the delivery force.

24. (original) The delivery device of claim 23, wherein the loading member comprises a loading button which is moved to a loaded position to load the biasing element with the delivery force and configured to be latched in the loaded position.

25. (currently amended) The delivery device of ~~any of claims 1 to 24~~ claim 1, wherein the bi-stable element of the actuating member has equal bi-stable states.

26. (currently amended) The delivery device of ~~any of claims 1 to 24~~ claim 1, wherein the bi-stable element of the actuating member has unequal bi-stable states, whereby the actuating force required to switch the bi-stable element to the actuated state is less than the force as would be required to switch the bi-stable element from the actuated state to the non-actuated state.

27. (currently amended) The delivery device of ~~any of claims 1 to 26~~ claim 1, wherein the actuating member further comprises a releasing element which is disposed to the bi-stable element thereof and configured to release the restraining member of the loading unit on actuation of the actuating member to the actuated state.

28. (currently amended) The delivery device of ~~any of claims 13 to 26 when appendant upon claim 12~~ claim 13, wherein the loading unit comprises a drive member which is actuatable from a loaded position to actuate the delivery unit, a biasing element for loading the drive member with the delivery force, and a restraining member for normally restraining the drive member in the loaded position and being configured to be released on actuation of the actuating member to the actuated state, such as to cause the biasing element to drive the drive member to actuate the delivery unit; and wherein the loading unit further comprises a releasing element which is operative, on actuation of the actuating member to the actuated state, to release the restraining member.

29. (currently amended) The delivery device of ~~claim 27 or 28~~ claim 27, wherein the releasing element comprises a cutter element.

30. (currently amended) The delivery device of ~~any of claims 1 to 29~~ claim 1, wherein the actuating member is configured such as substantially to close the air channel such that the actuating member is actuated on generation of a predeterminable pressure in the mouthpiece.

31. (currently amended) The delivery device of ~~any of claims 1 to 29~~ claim 1, wherein the actuating member is configured such as to provide for an air flow through the air channel when in the non-actuated state and close the air channel when in the actuated state.

32. (currently amended) The delivery device of ~~any of claims 1 to 29~~ claim 1, wherein the actuating member is configured such as substantially to close the air channel when in the non-actuated state and provide for an air flow through the air channel when in the actuated state.

33. (currently amended) The delivery device of ~~any of claims 1 to 29~~ claim 1, where the actuating member is configured such as to provide for an air flow at a first rate through the air channel when in the non-actuated state and an air flow at a second rate, higher than the first rate, through the air channel when in the actuated state.

34. (currently amended) The delivery device of ~~any of claims 1 to 33~~ claim 1, wherein the delivery device is a nasal delivery device, and further comprising: a nosepiece for fitting to a nostril of the subject through which substance is delivered into the nasal airway of the subject.

35. (currently amended) The delivery device of claim 34 ~~when appendant upon any of claims 31 to 33, wherein the actuating member is configured such as to provide for an air flow through the air channel when in the non-actuated state and close the air channel when in the actuated state; and~~ wherein the nosepiece is in fluid communication with the air channel such that an air flow which is delivered through the air channel is directed through the nosepiece.

36. (original) The delivery device of claim 35, further comprising: a pressure-sensitive release mechanism for providing for operation of the actuating member when a sufficient flow cannot be achieved through the nosepiece on exhalation by the subject into the mouthpiece.

37. (original) The delivery device of claim 36, wherein the pressure-sensitive release mechanism comprises a valve which is disposed downstream of the air channel and vents the air channel to atmosphere on generation of a predeterminable pressure in the mouthpiece.

38. (original) The delivery device of claim 37, wherein the pressure-sensitive release mechanism comprises a flexible diaphragm which is coupled to the actuating member, such that generation of a predeterminable pressure in the mouthpiece acts to deflect the diaphragm and actuate the coupled actuating member.

39. (original) A delivery device, comprising:
a delivery unit which is actuatable to deliver substance on application of a delivery force thereto; and
a loading unit which is actuatable to apply the delivery force to the delivery unit to actuate the same, the loading unit comprising a drive member which is actuatable from a loaded position to actuate the delivery unit, a biasing element for loading the drive member with the delivery force, and a restraining member for normally restraining the drive member in the loaded position and being configured to be broken on actuation of the loading unit to release the drive member and cause the biasing element to drive the drive member to actuate the delivery unit.

40. (original) The delivery device of claim 39, wherein the restraining member comprises a tether which is broken on actuation of the actuating member.

41. (original) The delivery device of claim 40, wherein the tether comprises at least one filament.

42. (original) The delivery device of claim 41, wherein the tether comprises a plurality of filaments.

43. (currently amended) The delivery device of claim 41 ~~or~~ 42, wherein the at least one filament comprises a strand.

44. (currently amended) The delivery device of claim 41 or 42, wherein the at least one filament comprises a sheet.

45. (currently amended) The delivery device of ~~any of claims 41 to 44~~ claim 41, wherein the at least one filament is formed of a notch-sensitive material.

46. (original) The delivery device of claim 45, wherein the at least one filament is axially stretched such as to be notch sensitized.

47. (original) The delivery device of claim 39, wherein the restraining member comprises a gas support cushion which is broken by rupturing of the same on actuation of the actuating member.

48. (currently amended) The delivery device of ~~any of claims 39 to 47~~ claim 39, further comprising: an actuating member which is actuatable to break the restraining member and actuate the loading unit.

49. (original) The delivery device of claim 48, further comprising:
a mouthpiece through which the subject in use exhales; and
an air channel which is in fluid communication with the mouthpiece; and
wherein the actuating member is disposed in the air channel such as to be actuated on exhalation by the subject, whereby the delivery device is a breath-actuated delivery device.

50. (original) The delivery device of claim 49, wherein the actuating member comprises a flexible, bi-stable element which is actuatable, on exhalation by the subject into the mouthpiece, between a first, non-actuated state and a second, actuated state in which the actuating member actuates the loading unit to apply the delivery force to the delivery unit to actuate the same.

51. (original) The delivery device of claim 50, wherein the actuating member further comprises a releasing element which is disposed to the bistable element thereof and configured to break the restraining member of the loading unit on actuation of the actuating member to the actuated state.

52. (original) The delivery device of claim 50, wherein the loading unit further comprises a releasing element which is operative, on actuation of the actuating member to the actuated state, to break the restraining member.

53. (currently amended) The delivery device of claim 51 ~~or 52~~, wherein the releasing element comprises a cutter element.

54. (currently amended) The delivery device of ~~any of claims 39 to 53~~ claim 39, wherein the delivery device is a nasal delivery device, and further comprising: a nosepiece for fitting to a nostril of the subject through which substance is delivered into the nasal airway of the subject.

55. (currently amended) The delivery device of claim 54 ~~when appendant upon any of claims 49 to 53, further comprising: a mouthpiece through which the subject in use exhales; and an air channel which is in fluid communication with the mouthpiece; and wherein the actuating member is disposed in the air channel such as to be actuated on exhalation by the subject, whereby the delivery device is a breath-actuated delivery device; and~~ wherein the nosepiece is in fluid communication with the air channel such that an air flow delivered through the air channel is directed through the nosepiece.

56. (original) A breath-actuated delivery device, comprising:
a mouthpiece through which a subject in use exhales;
an air channel which is in fluid communication with the mouthpiece; and
a flexible diaphragm which is disposed in the air channel, the diaphragm providing for at least a restricted air flow through the air channel until a predeterminable actuation

pressure is developed in the mouthpiece, and, on generation of the predeterminable actuation pressure in the mouthpiece, providing for an air flow through the air channel.

57. (original) The delivery device of claim 56, wherein the diaphragm at least substantially closes the air channel until the predeterminable actuation pressure is developed in the mouthpiece.

58. (original) The delivery device of claim 57, wherein the diaphragm closes the air channel until the predeterminable actuation pressure is developed in the mouthpiece.

59. (currently amended) The delivery device of ~~any of claims 56 to 58~~ claim 56, further comprising: a rupturing element for rupturing the diaphragm on generation of the predeterminable actuation pressure in the mouthpiece.

60. (currently amended) The delivery device of ~~any of claims 56 to 59~~ claim 56, wherein the diaphragm is a resilient element.

61. (currently amended) The delivery device of ~~any of claims 56 to 60~~ claim 56, wherein the delivery device is a nasal delivery device, and further comprising: a nosepiece for fitting to a nostril of the subject and through which substance is delivered to the nasal airway of the subject.

62. (original) The delivery device of claim 61, wherein the nosepiece is in fluid communication with the air channel, and an air flow, when delivered through the air channel, acts to entrain substance.

63. (original) A delivery device, comprising:
a delivery unit which is actuatable to deliver substance on application of a delivery force thereto; and
a loading unit which is actuatable to apply the delivery force to the delivery unit to actuate the same.

64. (original) A method of delivering substance to a nasal airway of a subject, the method comprising the steps of:
providing a delivery unit which is actuatable to deliver substance on application of a delivery force thereto;
loading a loading unit with the delivery force; and
actuating the loading unit to apply the delivery force to the delivery unit to actuate the same.

65. (original) A delivery device substantially as hereinbefore described with reference to any of Figures 1 to 3, Figures 4 and 5 or Figures 6 and 7 of the accompanying drawings.

66. (original) A method of delivering substance to a nasal airway of a subject substantially as hereinbefore described with reference to any of Figures 1 to 3, Figures 4 and 5 or Figures 5 and 7 of the accompanying drawings.